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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,339	08/31/2001	Edmund K. Waller	05010.0087U1	1418

7590 11/18/2002

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EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 11/18/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/945,339

Applicant(s)

WALLER ET AL.

Examiner

Michail A Belyavskyi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 May 2002 and 03 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 7-14 and 21-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 15-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

*Claims 1-58 are pending.*

1. Applicant's election with traverse of Group I (claims 1-6 and 15-20) and fludarabine as a species of a chemotherapeutic agent in Paper No. 8, filed on 5/24/02 and species of allogenic organ in Paper No. 10, filed on 09/03/02 are acknowledged.

Applicant traverse the Restriction Requirement on the grounds that the inventions must be both independent and distinct and an undue search burden on the examiner. However, MPEP 803 states that the Inventions be either independent or distinct and a burden on the Examiner if restriction is required. Regarding applicant's comments about undue burden, the MPEP 803 (August 2001) states that "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search". The Restriction Requirement enunciated in the previous Office Action meets this criterion and therefore establishes that serious burden is placed on the examiner by the examination Groups I-IV. The Inventions are distinct for reasons elaborated in paragraphs 3-5 of the previous Office Action.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7-14 and 21-58 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b), as being drawn to a nonelected invention.

*Claims 1-6 and 15-20 are under consideration in the instant application.*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-6 and 15 -20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waller (US Patent 5,800,539) in view of Sykes et al. (WO 99/25367).

Waller teaches a method of transplanting hematopoietic cells from a donor to genetically unrelated recipient that will inherently result in the enhancing immune reconstitution in the transplant recipient, comprising administering into the recipient in combination with the hematopoietic cells an amount of mononuclear cells, which are treated so reduce their ability to cause graft versus host disease effect, but which are retain their ability to facilitate engraftment of the hematopoietic cells in the recipient and administering to the recipient an effective amount of hematopoietic cells. (see entire document, Abstract and Claim 1 in particular). Waller also teaches that mononuclear cells are T cells, or natural killer (NK) cells, or mixture of T cells and NK cells ( overlapping column 3-4 and claims 2-4 in particular). Waller also teaches that mononuclear cells are treated with chemotherapeutic drugs, including fludarabine ( column 4, lines 66-67, column 5, lines 1-12 in particular). Walter teaches that said treated T cell should be viable and that this is essential for successful engraftment of donor hematopoietic cells (column 1, lines 45-60 in particular).

Walter do not explicitly teaches that said treated T cell retain their ability to proliferate in the recipient.

Sykes et al., teach a method of transplanting hematopoietic cells from a donor to genetically unrelated recipient , comprising treatment of donor T cells ( see entire document, page 5 lines 9-34 in particular ) Sykes et al., teach that for successful transplantation of hematopoietic cells from donor to recipient , it is essential that after treatment T cells are not completely depleted, thus so called graft-verses leukemia (GvL) effects of the non-depleted T cells help engraftment of donor hematopoietic cells ( see page 10, lines 17-23, page 11, line 5-25 in particular). Sykes et al., teach several treatment protocol, including treatment with fludarabine ( page 14, line 5-16 in particular). Sykes et al., specifically stressed that said treatment should not completely eliminated T cells (page 16, lines 2-11 in particular). Therefore it would be obvious to one of ordinary skill in the art at the time the invention was made to deduce that said non-eliminated T cells would be able to retain their ability to proliferate in the recipient.

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It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of Sykes et al., to those of Walter to obtain a claimed method of transplanting hematopoietic cells from donor to recipient, comprising administering into the recipient in combination with the hematopoietic cells an amount of mononuclear cells, which are treated so as to reduce their ability to cause graft versus host disease effect while retain their ability to proliferate in the recipient and facilitate engraftment of the hematopoietic cells in the recipient.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because one of ordinary skill in the art at the time the invention was made would deduce from the combined reference teaching that treatment of donor T cells in such a way as to retain not only their viability as taught by Walter, but also their ability to proliferate in the recipient, as taught by Sykes et al., would be essential for successful engraftment of donor hematopoietic cells. Such treatment can be used in the method of transplantation hematopoietic cells taught by Walter.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

4. No claim is allowed.

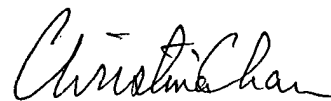
5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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Patent Examiner  
Technology Center 1600  
November 18, 2002:

  
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